UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,804	06/07/2001	Karoly Nikolics	P0576P1C2	1198

9157 7590 07/09/2002

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offic
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	8

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-59 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-59 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

* U.S. GPO: 1998-421-632/40206

Part III: Detailed Office Action

Notice: **Effective June 18, 2000**, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1647**.

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-6 and 30-36, drawn to pharmaceutical compositions of hormone receptors and methods of treatment, classified in Class 514, subclasses 8 and 12.

II. Claims 7-29, 42-48 and 52-59, drawn to nucleic acids, vectors, host cells, and a method for producing a hormone receptor, classified in Class 536, subclass 27 and Class 435, subclasses 69.1, 252.3, 240.2, and 172.3.

III. Claims 37-41, drawn to an assay for the detection of a hormone, classified in Class 436, subclass 503.

IV. Claims 49-51, drawn to antibodies and fragments thereof, including agonist and antagonists of hormone activity, classified in Class 530, subclasses 387 and 388 and Class 424, subclass 85.8.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the products can be made by chemical synthesis or purified from natural sources using conventional protein purification techniques including affinity chromatography, immunoaffinity chromatography, ion exchange chromatography, chromatofocusing, gel filtration and/or other conventional techniques and various combinations thereof.

The protein of group I and the DNA of group II are distinct chemical entities requiring non-

coextensive searches.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can also be used as a pharmaceutical.

Additionally, the pharmaceutical composition inventions of group I and the antibodies and antibody fragments of Group IV are related as distinct products. The antibodies and unobvious antibody fragments of Group IV include not only antibodies binding specifically to the receptors per se, but also having the unobvious activity of an agonist as well as an antagonist of hormone action.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, and because the searches for the individual Groups are not coextensive, restriction for examination purposes as indicated is proper.

Election of Species Requirements:

1. No claims are generic to a plurality of disclosed patentably distinct species comprising: (1) the LH/CG receptor of claims 1-4, 7-27, 30-32, 37-39, 42-44 and 47-51; (2) the FSH receptor of claims 1, 2, 5, 7-9, 28, 30, 33, 34, 37, 40, 42, 43, 45, and 47-59; and (3) the TSH receptor of claims 1, 2, 6-9, 29, 35-37, 41-43 and 46-51. Each of these receptors, while having some common properties with the others, involves separate considerations of in vivo utility and operability, antibody recognition as well as additional computer search burden. In addition to the aforementioned restriction requirement among the inventions of groups I-IV, applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

2. If, in response to the paragraph above, applicants elect LH/CG receptor, a further election of species is required:

This application contains claims directed to the following patentably distinct species of the claimed invention: each sequence identifier selected from the group consisting of SEQ ID NOS: 12-22 constitutes a patentably distinct species of LH/CG receptor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 7-21, 23-26, 30-32, 37-39, 42-44 and 47-51 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. With regard to Group I and either LH/CG or FSH receptor, if either is elected, claims 30, 31 and 33 are generic to a plurality of disclosed patentably distinct species comprising: the six conditions of claims 32 and 34, each of which requires separate considerations of in vivo utility, i.e. a burden of prosecution, and the burden of separate or additional computer searching. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, event though this requirement is traversed.

Should applicant traverse on the grounds that the species are not patentably distinct, applicant

should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined, including designation of all applicable elected species, even though the requirement be traversed. Further, applicants must clearly identify all claims corresponding to the elected invention and species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.

Lorraine Spector

Lorraine Spector, Ph.D.
Primary Examiner

LMS
09/877804.r
7/9/02